UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,142	10/09/2003	J. Michael Ramstack	000166.0073-US02	6453

26853 7590 02/14/2006

COVINGTON & BURLING
ATTN: PATENT DOCKETING
1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,142	RAMSTACK ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The indicated allowability of claim 23 is withdrawn upon reconsideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5, 6, 10-13, 15-17, 20-22, 24, 29 and 31-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Francois et al. US 6,555,544.

Francois discloses a method for preparing an aqueous suspension suitable for injection comprises mixing micronized risperidone with a liquid medium to form a premix, and mixing the premix with suspending agent such as sodium carboxymethyl cellulose (abstract; column 5, lines 52-55; and column 6, lines 54-67). The composition further comprises buffer, one or more preservative agent, and isotonizing agent (column 6, lines 54-61). Francois further discloses a method of administering the composition

for the treatment of a number of diseases in human (see abstract; and column 8, lines 8-20).

It is noted that Francois does not teach the viscosity of the suspending agent. However, it is the position of the examiner that the suspending agent taught by Francois would have the claimed viscosity, because Francois teaches the use of the same suspending agent, *e.g.*, sodium carboxymethyl cellulose, to obtain the same composition having the same viscosity, and for the same purpose, namely, an aqueous suspension suitable for injection through a needle into a host.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10-17, 19-22, 24 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. US 6,555,544.

Francois is relied upon for the reason stated above. Francois does not explicitly teach the viscosity of 200-600 cp at 20°C, as well as the claimed concentrations of the ingredients. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable concentrations of the ingredients, as well as suitable viscosity of the aqueous suspension, because Francois teaches the desirability of having an aqueous suspension composition that provides ease of administer, because Francois teaches an aqueous suspension having the claimed viscosity to provide injectability in fine needle with 21 gauge size (column 7, lines 35-44), and because Francois teaches the use of the same ingredients for the same purpose, *e.g.*, risperidone suspended in aqueous injection vehicle containing sodium carboxymethyl cellulose (viscosity enhancing agent).

Claims 1-7, 10-17, 22, 24 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. US 6,555,544, in view of Cho-Chung US 5,627,158.

Francois is relied upon for the reasons stated above. Regarding the viscosity of the injection suspension, Cho-Chung teaches using sodium carboxymethyl cellulose to increase the viscosity of the aqueous injection suspension (column 7, lines 5-16). Thus,

it would have been obvious to one of ordinary skill in the art to optimize the amount of sodium carboxymethyl cellulose to obtain a desired viscosity that is suitable for injection through a needle sizes from 18-22 gauge, because Francois teaches an injection suspension suitable for needle having diameter within the claimed range.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al. US 6,555,544, in view of Kitchell et al. US 5,486,362.

Francois is relied upon for the reasons stated above. Francois does not teach the steps of claims 8 or 9.

Kitchell teaches an injection suspension can be prepared by suspending microparticles of active in a solution comprising carboxymethyl cellulose. Kitchell further teaches a syringe containing the microparticles ca be used to draw up the pharmaceutical acceptable vehicle creating the suspension (column 9, lines 4-24). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Francois using the syringe to draw and mix the suspension, because Kitchell teaches the preparation can be done inside or outside the syringe.

Claims 18, 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francois et al., in view of Ramstack et al. WO 95/13799.

Francois is relied upon for the reasons stated above. Francois does not expressly teach the claimed polymeric binder. However, such polymeric binder is well known in pharmaceutical art, and thus, it would have been obvious to one of ordinary

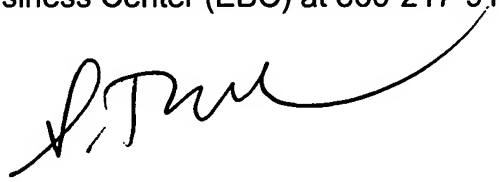
skill in the art to, by routine experimentation use the claimed polymeric binder. To be more specific, Ramstack is cited for the specific teaching of the use of the polymeric binder. Ramstack teaches a process for preparing biodegradable microparticles comprising biodegradable polymeric binder and active agent (see abstract). The microparticles are then suspended in an injectable liquid comprises 2.5% solution of carboxymethyl cellulose (page 29, lines 27-31). Active agent includes risperidone or 9-hydroxy risperidone (Fig. 8; page 8, lines 21-24; and examples). Polymeric binder includes poly(dl-lactide-co-glycolide) having the molar ratio of lactide to glycolide in the range of from about 85:15 to about 50:50 (page 16, lines 25-31). Thus, it would have been obvious to one of ordinary kill in the art to modify the microparticles of Francois using the polymeric binder in view of the teaching of Ramstack, because Ramstack teaches microparticles having size ranges from 25-180 μm (which is suitable for needle with diameter size ranging from 18-22 gauge), because Ramstack teaches the microparticles suitable for the same active agent taught by Francois, *e.g.*, risperidone, and because Francois teaches the use of surface modifier includes various polymer.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Tran
Patent Examiner
AU 1615